

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

In re: BAIR HUGGER FORCED AIR
WARMING DEVICES PRODUCTS
LIABILITY LITIGATION

MDL No. 15-2666 (JNE/DTS)

This Document Relates To:
All Actions

**PLAINTIFFS' RESPONSE
OPPOSING DEFENDANTS' RULE
37 MOTION TO BAR PLAINTIFFS'
EXPERTS**

INTRODUCTION

Before delving into the merits of Defendants' attempt to strike two of Plaintiff's experts, it is critical to consider the history of the litigation – where we came from, where we are currently, and what lies on the road immediately before this MDL.

Just over three years ago, Plaintiffs brought a motion to the Judicial Panel on Multidistrict Litigation ("JPML") to transfer cases pursuant to 28 U.S.C. § 1047 to the District of Minnesota. Defendants initially opposed creation of this MDL, arguing that the various district courts across the country were fully equipped to handle the growing litigation. The JPML transferred the cases to this Court in December of 2015.

A "Science Day" was held on May 19, 2016 to provide a basic framework for understanding the general scientific and medical issues acknowledged to be key to the ultimate resolution of this MDL. Beginning in the Summer of 2016 and continuing through March 20, 2017, the parties conducted certain permitted discovery on "general

causation” issues.¹ Through this general causation phase, less than 200,000 documents were produced by Defendants.² While this is a comparatively small universe of documents for a medical device that dates to the late 1980’s, there are some undeniable facts uncovered during this process. At least three merit reference here as the Court considers issues touching on general causation: (1) like its main competitor today - the Stryker Mistral³ - the original Bair Hugger included a warning about the risk of airborne contamination.⁴ For undisclosed reasons, and despite no company safety testing, that warning was removed when Defendants began marketing the Bair Hugger for use inside an operating room. (2) Since at least 2006, Defendants have admittedly internally both that Bair Hugger [REDACTED]

[REDACTED].⁶ To this day, Defendants continue to conceal those acknowledgements from the public. (3) Despite impassioned pleas of outrage to this Court, the FDA, and the medical community and public at large, the connection between Bair Hugger and airborne contamination causing infections was not newly fabricated by Augustine when he had a competing product to sell in 2010, but in truth was something known and discussed

¹ See Doc. 175.

² See Declaration of Genevieve M. Zimmerman. Presumably Defendants are honoring their obligations pursuant to the Federal Rules of Civil Procedure with respect to the ongoing duty to supplement their discovery responses with relevant and responsive documents that did not exist prior to the general causation cutoff or which were for some other reason not produced prior to the close of general causation discovery.

³ Ex. 1 (Stryker Mistral warning)

⁴ Ex. 2 (photo of Bair Hugger Model 200 warning).

⁵ Ex. 3 (Bair Paws 2007).

⁶ Ex. 4 (AVD doc with comment in the margin).

internally since at least 1994.⁷ These select admissions are relevant as the Court is presented with argument seeking to impose both a floor and a ceiling to expert reports to be used for the life of this MDL by redefining the meaning of “general causation”.

A. “General Causation”

General causation “has been defined by courts to mean whether the substance at issue had the capacity to cause the harm alleged, while “individual causation” refers to whether a particular individual suffers from a particular ailment as a result of exposure to a substance.” *In re Hanford Nuclear Res. Lit.*, 292 F.3d 1124 (9th Cir. 2002)(citing *Bonner v. ISP Technologies, Inc.*, 259 F.3d 924, 928 (8th Cir. 2001); *Sterling v. Velsicol Chemical Corp.*, 855 F.2d 1188, 1200 (6th Cir. 1988) (explaining the difference between generic and individual causation); *In re “Agent Orange”*, 818 F.2d at 165 (“[t]he relevant question . . . is not whether Agent Orange has the capacity to cause harm, the generic causation issue, but whether it did cause harm and to whom. That determination is highly individualistic, and depends on the characteristics of individual plaintiffs (e.g. state of health, lifestyle) and the nature of their exposure to Agent Orange”); *Jones v. Allercare, Inc.*, 203 F.R.D. 290, 301 (N.D. Ohio 2001)(“relevant question in this case will not be whether the products have the capacity to cause harm, but whether the products caused harm and to whom. Thus, the real causation issue in this case is individual, not general, in nature”)).

Put another way, the general causation stage of a case establishes a “floor,” or minimum standard for plaintiff’s proof in a given case or group of cases: is there credible,

⁷ Ex. 5 (Crazytown).

admissible evidence that the product at issue is capable of causing the harm complained of? If a court determines a plaintiff cannot meet their burden with respect to general causation, the litigation comes to a halt. If that hurdle is cleared, as is the case in this MDL, cases proceed forward to the next stage, where each individual plaintiff – such as Ms. Axline – then has to go beyond what was required in the general causation stage to establish a genuine issue of material fact with respect to whether their asserted individual damages were legally caused by the product at issue. What may be required from any given plaintiff may vary from state to state, depending on choice of law determinations, time of exposure, etc.

Plaintiffs' expert reports on general causation were timely produced on March 31, 2017. Defendants' rebuttal reports on general causation were produced on June 3, 2017. Experts for each side were deposed by August of 2017, leading up to dispositive motion practice on general causation in the Fall. Plaintiffs brought *Daubert* motions seeking to exclude each of Defendants' proffered experts on general causation, including Dr. John Abraham.⁸ Defendants also sought to exclude each of Plaintiffs' general causation experts. The Court denied all of the *Daubert* motions, as well as Defendants motion for summary judgment on general causation issues.⁹ With Plaintiffs' obligations with respect

⁸ See Doc. 821. Plaintiffs' motion to exclude Dr. Abraham was based in part on Dr. Abraham's testimony averring he is not an expert in the movement of particles in turbulent flow. See Doc. 823-2 (Abraham Dep. 246:3-8). Plaintiffs' motion to exclude Dr. Abraham pursuant to *Daubert* was also based in substantial part on his failure to identify a methodology underlying the opinions he intended to offer, (71:9-13; 253:14-254:5), and on the fact Abraham admitted he permanently deleted all the files that would demonstrate the equations he claimed to have solved to address the question about the impact of the Bair Hugger on movement of squame sized particles in a turbulent operating room. *Id.* at 52:20-51:23.

⁹ Doc. 1024.

to general causation satisfied, the Court and the parties proceeded to trial in May of 2018. While the general causation discovery process was playing out, the Court randomly selected 100 cases for bellwether consideration in late 2016,¹⁰ and another 150 cases for bellwether consideration in early 2018.¹¹

B. Bellwether Trials

According to the Manual for Complex Litigation, if “bellwether trials or test cases, are to produce reliable information about other [. . .] cases, the specific plaintiffs and their claims should be representative of the range of cases” *Manual for Complex Litigation, Annotated* §22.315(2015). Indeed, the purpose of bellwether trials is to “produce a sufficient number of representative verdicts” to “enable the parties and the court to determine the nature and strength of the claims, whether they can be fairly developments and litigated on a group basis and what range of values the cases may have is resolution is attempted on a group basis.” *Id. See also* Eldon E. Fallon, et. al., *Bellwether Trials in Multidistrict Litigation*, 82 TUL. L. REV., 2323, 2343 (2008)(“the trial selection process should . . . illustrate the likelihood of success and measure of damages” and “[a]ny trial-selection process that strays from this path will likely resolve only a few independent cases and have a limited global impact.”). Bellwether trials are most useful if they assist the parties in assessing the strengths and weaknesses of various types of claims pending in a given MDL.

¹⁰ Doc. 143.

¹¹ Doc. 1061.

Defendants' instant motion essentially begs this Court to apply a form of collateral estoppel to Axline and all future cases, ordering that each plaintiff is bound to offer only that expert testimony disclosed in reports during the initial general causation phase; Defendants ask this Court to adopt a rule defining "general causation" as both a floor and a ceiling governing experts used throughout this MDL. But this is not a class action. This MDL has always contemplated more than one bellwether trial. The parties are likely to continue to refine discovery requests, direct and cross-examination, trial themes and strategies until the close of this litigation, whenever that may be. If any trials are to be true bellwether trials, such that the trials import meaning to the Court and to the parties about the "true nature and strength of the claims" and defenses asserted as Judge Fallon counsels in his article, Plaintiffs must, respectfully, be allowed to introduce evidence establishing negligence, failure to warn, and the knowledge and conduct of the Defendants. Similarly, Plaintiffs must be afforded a fulsome opportunity to present his or her case with respect to long known reasonable alternative designs and warnings. Any order striking timely disclosed expert reports at this juncture risks the very foundation of the upcoming "bellwether" trial.

C. Case Specific Causation

Previous CMOs contemplated experts may provide more than one report. See CMO 25 – (“(d) If an expert has testified about general causation, a party deposing [sic] that expert witness may not explore general causation unless as incidental to a specific causation inquiry”). Plaintiff Axline submitted her expert reports timely, and could not have reasonably anticipated, based on the language in previous CMOs, that her case may

be subject to dismissal or significant limitation on the grounds that she failed to provide an individualized, comprehensive summary of all methods of establishing and/or maintaining patient normothermia (to the extent that goal is necessary at all). *See In re Hanford Nuclear Res. Lit.*, 292 F.3d 1124 (9th Cir. 2002). Plaintiffs have previously provided experts establishing general causation: that Bair Hugger is capable of causing the types of injuries alleged by plaintiffs as a general matter, and that reasonable alternatives exist.¹² Plaintiff Axline has now timely disclosed expert reports detailing both case specific causation opinions on medical issues as well as a supplement on issues of reasonable alternative design. The general causation phase was never intended or understood as a ceiling for expert testimony. Indeed, there is no obligation that any given plaintiff use some or all of the experts disclosed during the general causation phase; given this MDL is now comprised of nearly 5,000 cases, it is difficult to imagine any expert has sufficient availability to provide case specific testimony on each of the cases coordinated before this Honorable Court. Plaintiffs respectfully submit that the Court should decline to adopt a new limitation in that regard at this stage of this litigation.

Defendants complain that disclosure of Dr. Yadin David's supplemental report detailing additional reasonable alternative designs and products put them at a disadvantage because Defendants are precluded from conducting third party discovery

¹² See Doc. 1024 (Order denying *Daubert* challenges, finding plaintiffs' experts who concluding that Bair Hugger is capable of causing deep-joint infection are qualified and admissible as they followed appropriate, reliable methodology in arriving at their opinions. The Order also denied Defendants' summary judgment motion).

with respect to these alternative designs.¹³ This complaint rings hollow for several reasons. First, these alternative methods of maintaining patient normothermia have long been known to Defendants.¹⁴ Second, even if Defendants learned for the first time about these alternative methods of achieving normothermia in Plaintiffs' expert reports, under each of the Court's scheduling orders, discovery on "general causation" closed prior to the deadline for disclosure of Plaintiffs' general causation expert reports.¹⁵ Given that deadline, Defendants were never in a position to conduct third-party discovery based on the content of any of Plaintiffs' general causation expert reports. The scheduling orders never proscribed a limitation as to which experts any individual plaintiff may call in their individual cases as trials are scheduled.

i. Dr. Yadin David's Supplement is Proper

During the general causation stage, Plaintiffs offered a report from Dr. Yadin David which details in relevant part the existence of reasonable alternative designs capable of achieving or maintaining patient normothermia and/or avoiding the risks associated with use of the Bair Hugger patient warming system. As part of the general causation phase of this MDL, Plaintiffs were to establish for this Court that they have qualified, reliable, admissible expert testimony with respect to claims of strict liability for design defect and failure to warn, etc. The Defendants are correct that it is Plaintiffs' burden to establish the existence of a feasible safer alternative design under the laws of

¹³ Doc. 1436 at 2.

¹⁴ See Ex. 6 (3MBH01726344)(Email from Jay Issa attaching color coded chart comparing patient warming modalities); Ex. 7 (3M00639100)(July 2013 "Review of Current Competitors"); Ex. 8 (PowerPoint comparing BH to other warming modalities).

¹⁵ See Doc. 175 at (PTO 17, Jan. 5, 2017).

many states.¹⁶ Plaintiffs succeeded in demonstrating for this Court that they have credible, qualified, admissible testimony supporting the allegations made in the master long form complaint. At no point, however, did this Court limit the parties' ability to supplement general causation reports, nor did the scheduling orders setting deadlines for disclosure of general causation opinions limit the Plaintiffs to only the experts disclosed during the general "can this happen" phase of the case during case specific discovery and trial. Thus, Plaintiffs were not required to produce Dr. David's opinions regarding the universe of design alternatives in the general causation phase. The opinions Dr. David expresses in his supplemental report are timely disclosed pursuant to the scheduling order governing Axline, and serves as a supplement to the opinions he previously offered in the general causation phase. Defendants have been offered a full opportunity to explore both the opinions he has supplemented and the basis for those opinions so no prejudice attaches.

Even if this Court is inclined to fashion a new rule, finding that "general causation" sets both a floor and a ceiling for expert reports, Rule 37 does not suggest that sanctions are appropriate. Rather, courts are to consider whether there is surprise and/or prejudice to the opposing party, the extent to which the testimony would disrupt trial, and the importance of the information or testimony. *Wegener*, 527 F.3d at – (citing *Sellers v. Mineta*, 350 F.3d 706, 711-12 (8th Cir. 2003) and *Marti v. City of Maplewood*, 57 F.3d 680, 683 (8th Cir. 1995)). Striking an expert is excluding evidence, and when that result may be tantamount to dismissal of certain claims, a district court should consider lesser

¹⁶ Doc. 1436 at 6.

sanctions. *See Heartland Bank v. Heartland Home Fin., Inc.*, 335 F.3d 810, 817 (8th Cir. 2003). Striking Dr. David's supplemental report and opinions is equivalent to striking significant evidence of alternative designs/products, which is necessary under the laws of many states.

Even if Dr. David's supplemental report was to be deemed untimely, the lack of disclosure during the general causation phase of the case is substantially justified given that discovery in to alternative designs that were not considered forced air warmers were precluded as irrelevant under Minnesota law in the general causation phase.¹⁷ However, on the eve of the Gareis trial, the Court indicated a change in the ruling about available alternative products in light of South Carolina law. There is thus a change in circumstances that has occurred since the general causation phase and the case-specific work up of Mr. Gareis's case and now Ms. Axline's.

Regardless, any timing of Dr. David's supplemental disclosure is harmless. Each of the alternative designs and products which are included in Dr. David's general causation report in March of 2017 and his supplemental report of August 2018 are well known to Defendants. Indeed, Defendants have conducted comparative testing and have touted reported benefits of the Bair Hugger as compared to these products for years. Defendants could not rely on the disclosure of reasonable alternative designs by Plaintiffs' experts in determining what third party discovery might be sought, as the general causation discovery deadline had always expired prior to the disclosure of Plaintiffs' expert reports. Defendants' experts have arrived at each of their depositions –

¹⁷ Doc. 249; Doc. 304.

in both the general causation and case specific causation phases - with sometimes in excess of two-dozen new articles, each of which predated their expert reports. Indeed, in *Gareis*, Defendants' experts were permitted to testify to entirely undisclosed opinions. Defendants suffer no actual prejudice by the supplemental report of Dr. David. Thus, under Federal Rule of Civil Procedure 37, relied on by Defendants, any failure to timely disclose was substantially justified or is harmless and sanctions are inappropriate here.

ii. Dr. Nathan Bushnell's Testimony and Opinions are Proper Rebuttal

Rule 26 does not require the disclosure of evidence used solely for impeachment purposes. *See Wegener v. Johnson*, 527 F.3d 687, 691 (8th Cir. 2008) (citing Fed. R. Civ. P. 37(c) advisory committee's note (1993)). Difficulty has arisen, however, in distinguishing between "foundational facts and expert opinion, and [also] to distinguish between impeachment and substantive evidence", so "Rule 26(a)(2)(C)(ii) resolves the dilemma in favor of disclosure." *Id.* (citations omitted).

Plaintiffs concede that Dr. Bushnell is a rebuttal expert, but not a "sur-rebuttal" expert. The Seventh Circuit has explained the role of rebuttal evidence: "[t]he proper function of rebuttal evidence is to contradict, impeach or defuse the impact of the evidence offered by an adverse party." *Peals v. Terre Haute Police Dept.*, 535 F.3d 621, 630 (quoting *United States v. Grintjes*, 237 F.3d 876, 879 (7th Cir. 2001) (internal quotation marks omitted)).

In an abundance of caution, Plaintiffs have disclosed a written report from Dr. Bushnell detailing his anticipated impeachment of Dr. Abraham. Dr. Bushnell will be

called as a rebuttal expert if Dr. Abraham is called to testify at the *Axline* trial or other matters.¹⁸ Dr. Bushnell's report was drafted and finalized in the Summer of 2018, and timely served pursuant to the "initial expert reports" deadline set by this Court in the *Axline* scheduling order.¹⁹ Defendants have been offered the opportunity to depose Dr. Bushnell if they wish to understand his methodologies, conclusions and criticisms in greater detail.²⁰ This written disclosure of Dr. Bushnell's rebuttal expert testimony puts Defendants at a distinct *advantage* – not disadvantage – as they have a detailed report that includes specific criticisms, shortcomings, and outright errors contained in Dr. Abraham's report. Plaintiffs have offered further advantage in the form of the opportunity to depose Dr. Bushnell with respect to his report and the opinions he expresses therein. Defendants can take or leave that opportunity but cannot claim disadvantage. Plaintiffs are entitled to rebut evidence and testimony Defendants may offer at trial. Dr. Bushnell's report provides a detailed road map of what that rebuttal testimony will include should Dr. Abraham be called to the stand in future trials.

Regardless, Defendants' claim that Plaintiffs' alleged violation of the Court's prohibition against sur-rebuttal reports subjects them to Rule 37(b)(2)(A) is misplaced. That Rule provides: "If a party or a party's officer, director, or managing agent—or a witness designated under Rule 30(b)(6) or 31(a)(4)—fails to obey **an order to provide**

¹⁸ Indeed, Plaintiffs expressly reserve the right to call Dr. Bushnell at trial to impeach Dr. Abraham's testimony in *Axline*, or at any other trial where Dr. Abraham may be called in the future.

¹⁹ Doc. 1188.

²⁰ Defendants requested dates in the first two weeks of September for deposition of Plaintiff's experts, and Plaintiff offered September 7th for Dr. Bushnell's deposition. By email dated August 29, 2018, Defendants have declined to depose Dr. Bushnell citing this pending motion before the Court.

or permit discovery, including an order under Rule 26(f), 35, or 37(a), the court where the action is pending may issue further just orders.” Fed. R. Civ. P. 37(b)(2)(A) (emphasis added). The rule expressly applies only in cases in which an order to provide or permit discovery is disobeyed. If Defendants are to be believed, the opposite is true with respect to Dr. Bushnell’s anticipatory disclosure of rebuttal opinions. Thus, Rule 37 does not apply.

CONCLUSION

Plaintiffs’ supplemental expert report from Dr. Yadin David does not prejudice Defendants, nor does the anticipatory disclosure of rebuttal opinions from Dr. Nathan Bushnell. Defendants have been offered the opportunity to depose Plaintiffs’ experts with sufficient time to explore their opinions, and to bring appropriate challenges, if any, regarding qualifications and methodology in a timely manner in advance of trial in December. Plaintiffs respectfully request this Court decline to establish an unprecedented rule that “general causation” reports serve as both a floor and a ceiling for all subsequent bellwether plaintiffs, and for the foregoing reasons, the Plaintiffs respectfully request the Court deny Defendants’ Motion.

Respectfully submitted,

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